



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David R. Milich *et al.*
Serial No.: 10/630,074
Filed: 07/30/2003
Entitled: Human Hepatitis B Virus Core Proteins As Vaccine
Platforms And Methods Of Use Thereof

Group No.:
Examiner:

INFORMATION DISCLOSURE
STATEMENT TRANSMITTAL

Commissioner for Patents
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Dated: 10-29-2003

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PATENT

Attorney Docket No. VACCINE-07971

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By: 

Cliff Cannon-Cin

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following patents are referred to in the body of the specification:

- WO 02/13765 published 12/21/02;
- U.S. Patent No. 4,683,195 issued 7/28/87 to Mullis *et al.*
- U.S. Patent No. 4,683,202 issued 7/28/87 to Mullis; and
- U.S. Patent No. 4,965,188 issued 10/23/90 to Mullis *et al.*

The following printed publications are referred to in the body of the specification:

- Pumpens and Grens (2001) "HBV Core Particles as a Carrier for B Cell/T Cell Epitopes," Intervirology 44:98-114;

- Jegerlehner *et al.* "A molecular assembly system that renders antigens of choice highly repetitive for induction of protective B cell responses," (2002) *Vaccine* 20:3104;
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Applicants have become aware of the following printed publications which may be material to the examination of this application:

- U.S. Patent No. 6,602,705 issued 8/5/03 to Barnett *et al.*;
- U.S. Patent No. 6,406,705 issued 6/18/02 to Davis *et al.*;
- U.S. Patent No. 6,231,864 issued May 15, 2001 to Birkett;
- U.S. Patent No. 4,599,230 issued July 8, 1986 to Milich *et al.*;
- U.S. Patent No. 4,599,231 issued July 8, 1986 to Milich *et al.*;
- U.S. Patent No. 4,683,136 issued July 8, 1987 to Milich *et al.*;
- U.S. Patent No. 5,726,011 issued March 10, 1998 to Milich *et al.*;
- U.S. Patent No. 4,818,527 issued April 4, 1989 to Thornton *et al.*;
- U.S. Patent No. 4,882,145 issued November 21, 1989 to Thornton *et al.*;
- U.S. Patent No. 5,143,726 issued September 1, 1992 to Thornton *et al.*;
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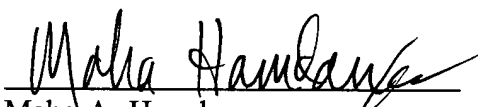
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- Birkett, U.S. Patent Application No. 09/930,915, filed Aug. 15, 2001, published July 24, 2003 as Publication No. 20030138769, and entitled "Immunogenic HBc chimeric particles having enhanced stability," and

- Brown *et al.*, U.S. patent publication No. US 20030175296 published Sept. 18, 2003, and entitled "Chimaeric hepadnavirus core antigen proteins."

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Draw additional Sheets If Necessary)

Applicant: David R. Milich *et al.*

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Group Art Unit:

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U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. | Serial / Patent Number | Issue Date | Applicant / Patentee | Class | Subclass | Filing Date |
|-------------------|----------|------------------------|------------|------------------------|-------|----------|-------------|
| | 1 | 4,683,195 | 7/28/87 | Mullis <i>et al.</i> | | | |
| | 2 | 4,683,202 | 7/28/87 | Mullis | | | |
| | 3 | 4,965,188 | 10/23/90 | Mullis <i>et al.</i> | | | |
| | 4 | 6,602,705 | 8/5/03 | Barnett <i>et al.</i> | | | |
| | 5 | 6,406,705 | 6/18/02 | Davis <i>et al.</i> | | | |
| | 6 | 6,231,864 | 5/15/01 | Birkett | | | |
| | 7 | 4,599,230 | 7/8/86 | Milich <i>et al.</i> | | | |
| | 8 | 4,599,231 | 7/8/86 | Milich <i>et al.</i> | | | |
| | 9 | 4,683,136 | 7/8/87 | Milich <i>et al.</i> | | | |
| | 10 | 5,726,011 | 3/10/98 | Milich <i>et al.</i> | | | |
| | 11 | 4,818,527 | 4/4/89 | Thornton <i>et al.</i> | | | |
| | 12 | 4,882,145 | 11/21/89 | Thornton <i>et al.</i> | | | |
| | 13 | 5,143,726 | 9/1/92 | Thornton <i>et al.</i> | | | |

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

| | | Document Number | Publication Date | Country / Patent Office | Class | Subclass | Translation | |
|--|----|-----------------|------------------|-------------------------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | 14 | WO 02/13765 | 12/21/02 ✓ | PCT | | | | |
| | 15 | WO 01/98333 A2 | 12/27/01 ✓ | PCT | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

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| 16 ✓ | Pumpens and Grens (2001) "HBV Core Particles as a Carrier for B Cell/T Cell Epitopes," <i>Intervirology</i> 44:98-114 |
| 17 ✓ | Jegerlehner <i>et al.</i> "A molecular assembly system that renders antigens of choice highly repetitive for induction of protective B cell responses," (2002) <i>Vaccine</i> 20:3104 |
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| 19 ✓ | Smith and Waterman (1981) "Comparison of Biosequences," <i>Adv. Appl. Math.</i> 2: 482-489 |
| 20 ✓ | Needleman and Wunsch (1970) "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," <i>J. Mol. Biol.</i> 48: 443-453 |
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